

REMARKS

Claims 43-56 and 62-78 are pending in the application.

Claims 43-56 and 62-78 have been rejected.

Claims 43-45, 62, 63, 67, 71 and 75 have been amended, as set forth herein.

I. AMENDMENTS TO CLAIMS 43-45, 62, 63, 67, 71 and 75

Applicant has amended Claims 43-45, 62, 63, 67, 71 and 75 to recite, generally, that one of the end portions (either the proximal end portion or the distal end portion) of the lead includes the openings/tunnels/regions, as claimed. Thus, the recited multiple openings/tunnels/regions from one electrode to a corresponding conductor are positioned at a specified one of the end portions. These amendments have been made solely to clarify the subject matter of the claimed invention, and have not been made for reasons related to patentability.

II. REJECTION UNDER 35 U.S.C. § 103

All pending claims were rejected under 35 U.S.C. § 103(a) under various theories. The rejections are respectfully traversed.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP §

2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

- A. Claims 43, 44, 52, 53, 62, 63, 67-69, 71-73 and 75-78 rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian, et al. (US 5,796,044) in view of Iwaszkiewicz, et al (US 4,590,950)

Cobian recites a first coiled wire conductor connected at one end to a first electrode and a second coiled wire conductor connected at the end to a second electrode. As noted in the Office Action, Cobian's conductors are equally spaced from the longitudinal axis of the lead, but Cobian fails to disclose multiple conductive links within openings/tunnels in the lead body wall for electrically connecting a conductor to an electrode (i.e., fails to disclose Applicant's two conductive links electrically connecting the same electrode to the conductor at one end of the lead).

The Office Action argues that Iwaszkiewicz teaches using first and second openings with first and second conductive links connecting a ring electrode to a conductor "to provide a redundant connection for connecting the ring electrode to the conductor and to provide an easily manufactured, flexible lead," and therefore it would be obvious to modify Cobian's lead to include first and second openings in the lead wall and first and second conductive links to connect the electrode to the conductor. See, Office Action, page 3 ("to provide a redundant connection").

However, Applicant respectfully submits that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

Iwaszkiewicz discloses two conductors, with each conductor (1) spaced at a different distance (or layer) from the longitudinal center of the lead body, and (2) constructed of a coiled wire with no spacing between the wrapped coils to allow multiple conductors in that particular

layer, and (3) failing to include insulation around each conductor (unlike Cobian, which utilizes separately insulated conductors. Thus, Iwaszkiewicz teaches away from using multiple conductors intertwined at the same layer (i.e., about the same distance from the longitudinal center) as recited in Cobian. This fact, alone, leads to the conclusion that there exists no suggestion, teaching or motivation to combine the two references. The proposed addition of the two wires 20 (as taught by Iwaszkiewicz) to Cobian does not appear to be practical, and would likely lead to additional problems in manufacturing such a lead - as it is not clear how the two wires would be placed to avoid contact with an adjacent conductor (if uninsulated conductors are used), or how (or when) Cobian's insulated conductors would be stripped at the exact location of the inner portion of the wire 20 (of Iwaszkiewicz).¹

In addition, Iwaszkiewicz recites that "the conductive bridge comprises two such wires 20 symmetrically disposed relative a cross section of the lead . . . However, a single wire, or more than two wires may be employed . . ." (Col. 4, lines 45-49; see also Col. 5, lines 9-15). As a result, Applicant respectfully submits that a person of ordinary skill in the art would not view Iwaszkiewicz as teaching or suggesting using multiple connections for redundancy

¹ During the examiner interview, the Examiner raised the argument that it would be inherent to strip the conductors of Cobian and combine with Iwaszkiewicz.. Applicant respectfully disagrees. Iwaszkiewicz slides the single, bare coiled conductor (as a separate element) through the outer insulator (after the wires 20 are inserted through the insulator). In distinct contrast, Cobian's conductor is insulated. Thus, an additional step of stripping the Cobian insulated conductor would be necessary (in addition to cutting an opening in the outer insulator).

purposes.² Importantly, Applicant also uses multiple conductive links between the conductor and electrode to insure a low ohmic coupling between the two. See, Applicant's Specification, page 9, line 28 thru page 10, line 3. Neither Cobian or Iwaszkiewicz teaches this benefit of Applicant's invention.³

Therefore, the proposed Cobian-Iwaszkiewicz combination fails to disclose, teach or suggest Applicant's claimed invention.

B. Claims 43, 44, 52, 53, 62, 63, 67-69, 71-73 and 75-78 rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwaszkiewicz, et al (US 4,590,950)

As clearly illustrated in Applicant's prior response, since each of the independent Claims 43, 62, 63, 67, 71 and 75 recite first and second conductors that are each spaced about the same distance from a longitudinal axis of the body member (or spaced substantially equidistant from the axis of the lead body), mere "duplication" of Iwaszkiewicz' single conductor would not

² This fact is further evident as Iwaszkiewicz fails to teach (or stress any importance of) the use of multiple connections to connect the other conductor 21 to the distal electrode tip 12. See, Col. 6, lines 9-14. Thus, Iwaszkiewicz does not readily teach multiple connection points between an electrode and its corresponding conductor for redundancy purposes.

³ Applicant notes that Cobian recites that "additional wires can be intertwined into the depicted coil to accommodate additional electrodes or make the electrical connections redundant" (Col. 9, lines 25-30). Thus, Cobian contemplates using multiple coiled conductors (extending through the lead body) to provide a redundant connection between the electrode at one end and the electrode at another end, thereby not utilizing multiple connections to the same conductor. Applicant's invention is therefore more advantageous, in that Applicant may use each conductor for a separate electrode with multiple conductive links between the electrode and conductor.

result in Applicant's invention, as claimed. The disclosure of Iwaszkiewicz fails to allow "duplication" of the single conductor shown in Iwaszkiewicz as the conductor is illustrated as coiled, virtually unitary (no spacings between the wire), and extends substantially the length of the lead. Accordingly, there cannot be two such conductors that are "spaced about the same distance from a longitudinal axis of the body member" (or substantially equidistant from the axis). As such, Applicant respectfully submits that "duplication" of Iwaszkiewicz' single conductor cannot produce the Applicant's claimed invention (as stated previously, duplication of Iwaszkiewicz is substantially problematic), and the Office Action's general assertion (page 5) of obviousness is merely conclusory, and fails to establish a prima facie case of obviousness.⁴

Therefore, these claims are not obvious in view of Iwaszkiewicz.

C. Claims 54, 66 and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwaszkiewicz, et al. (US 4,590,950)⁵

These claims are dependent claims. For the same reasons set forth above, Claims 54, 66 and 70 are not obvious in view of Iwaszkiewicz.

⁴ This 103 rejection simply argues that "it is known in the art" to have multiple conductors at about the same distance from the longitudinal axis of the body member. This, in essence, is the Office Action's 103 rejection over Cobian and Iwaszkiewicz.

⁵ The Office Action also appears to reject these claims under Section 102. However, these claims are dependent claims, and the Office Action has not rejected under Section 102 any of the independent claims upon which Claims 54, 66 and 70 depend. As such, Applicant believes that the Office Action's reference to Section 102 was inadvertent.

- D. Claims 45-50 and 56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwaszkiewicz, et al (US 4,590,950)

These claims are dependent claims. For the same reasons set forth above, Claims 45-50 and 56 are not obvious in view of Iwaszkiewicz.

- E. Claims 51, 64, 74 and 77 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwaszkiewicz, et al (US 4,590,950) in view of Willis (US 5,433,742) or Gotthardt, et al. (US 5,016,646).

These claims are dependent claims. For the same reasons set forth above the proposed combination of Iwaszkiewicz and Willis (or Gotthardt) do not cure the deficiencies of Iwaszkiewicz.

- F. Claim 55 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Iwaszkiewicz, et al (US 4,590,950)

This claim is a dependent claims. For the same reasons set forth above, Claim 55 is not obvious in view of Iwaszkiewicz.

In sum, Applicant respectfully requests withdrawal of the § 103(a) rejections of Claims 43-56 and 62-78.

II. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at *rmccutcheon@davismunck.com*.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

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